International Medical Technology Regulatory Harmonization and Healthcare System Strengthening

Strengthening Healthcare Systems:
Meeting the Challenges through Innovation, Ethics and Trade
Broader Pacific Dialogue: Health Care Focus

San Jose, Costa Rica; 17 April 2013

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Thesis

Health care systems depend upon medical technology

- Diagnostic and therapeutic
- Low and high tech
- Hospitals, clinics, homes

Thesis

Enlightened, appropriate, judiciously applied regulation of health care products is a public good

- Protection and promotion of public health
- Good governance
- Expectation of citizens
- Public confidence in products
- Essential in protecting and advancing public health, promoting innovation, and facilitating international trade

Thesis

Regulation and regulatory practice are determinants of successful life sciences innovation

- Regulators are on the life sciences “critical path”
- The efficiency and effectiveness of a regulatory authority in fulfilling its public health mandate is therefore critical to achievement of desired life sciences outcomes

Thesis

Regulator-to-regulator cooperation, international regulatory harmonization, and use of international standards are important enablers of patient access to safe and effective medical technology of high quality

Regulatory harmonization

Simple in concept …

> "The establishment, recognition and application of common standards and regulatory measures"
>
> (World Trade Organization)

… more difficult in execution

Definitions – GHTF

"The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by those regulatory means considered the most suitable. ...

Source: Global Harmonization Task Force (GHTF); *The GHTF Regulatory Model*; , GHTF/AHWG-GRM/N1R13:2011; April 2011

Definitions – GHTF

... The purpose of such guidance is to provide a regulatory framework that would help eliminate differences between jurisdictions, decrease the cost of gaining regulatory compliance, allow patients, users, and others earlier access to new technologies and treatments and maintain a safe and effective level of healthcare over time through efficient post-market surveillance."

Source: Global Harmonization Task Force (GHTF); *The GHTF Regulatory Model*; , GHTF/AHWG-GRM/N1R13:2011; April 2011

Definitions – IMDRF

Regulatory convergence: "… a voluntary process whereby the regulatory requirements and approaches across regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. …"

Source: International Medical Device Regulators Forum (IMDRF); *Terms of Reference,* March 2012

Definitions – IMDRF

“ … The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.”

Source: IMDRF Terms of Reference, 1 March 2012

Definitions

- Regulatory harmonization: Progressive voluntary convergence in technical regulatory requirements

Definitions

- Regulatory harmonization: Progressive voluntary convergence in technical regulatory requirements
- Not:
  - International regulation
  - Standardization
  - Mutual recognition
  - Verbatim adoption of same text in laws, regulation, and guidance
  - ‘Approved once, accepted everywhere’

Regulatory convergence

Convergence on harmonized:

- Regulatory requirements
- Evidence requirements
- Forms and format of evidence
  → Similar review practices

Not necessarily:

- Acceptance criteria
- Decisions by regulatory authority or conformity assessment body

Why seek regulatory convergence?

Regulatory harmonization in support of public health

- Most countries cannot afford regulatory systems of complexity and expense of advanced economies
- Helps develop and disseminate regulatory knowledge and best practices
- Promotes wider sharing of expertise
- Contributes to regulatory risk assessment and management
- Recognizes global nature of supply chains

Why seek regulatory convergence?

Regulatory harmonization in support of public health

- Helps reduce burdens on regulators and manufacturers/applicants
- Offers replacement of multiple submission formats with a single harmonized format (pre- and post-market submissions)
- Offers possibility of common electronic submission format
- Offers greater acceptance of clinical evidence

Why seek regulatory convergence?

Regulatory harmonization in support of public health

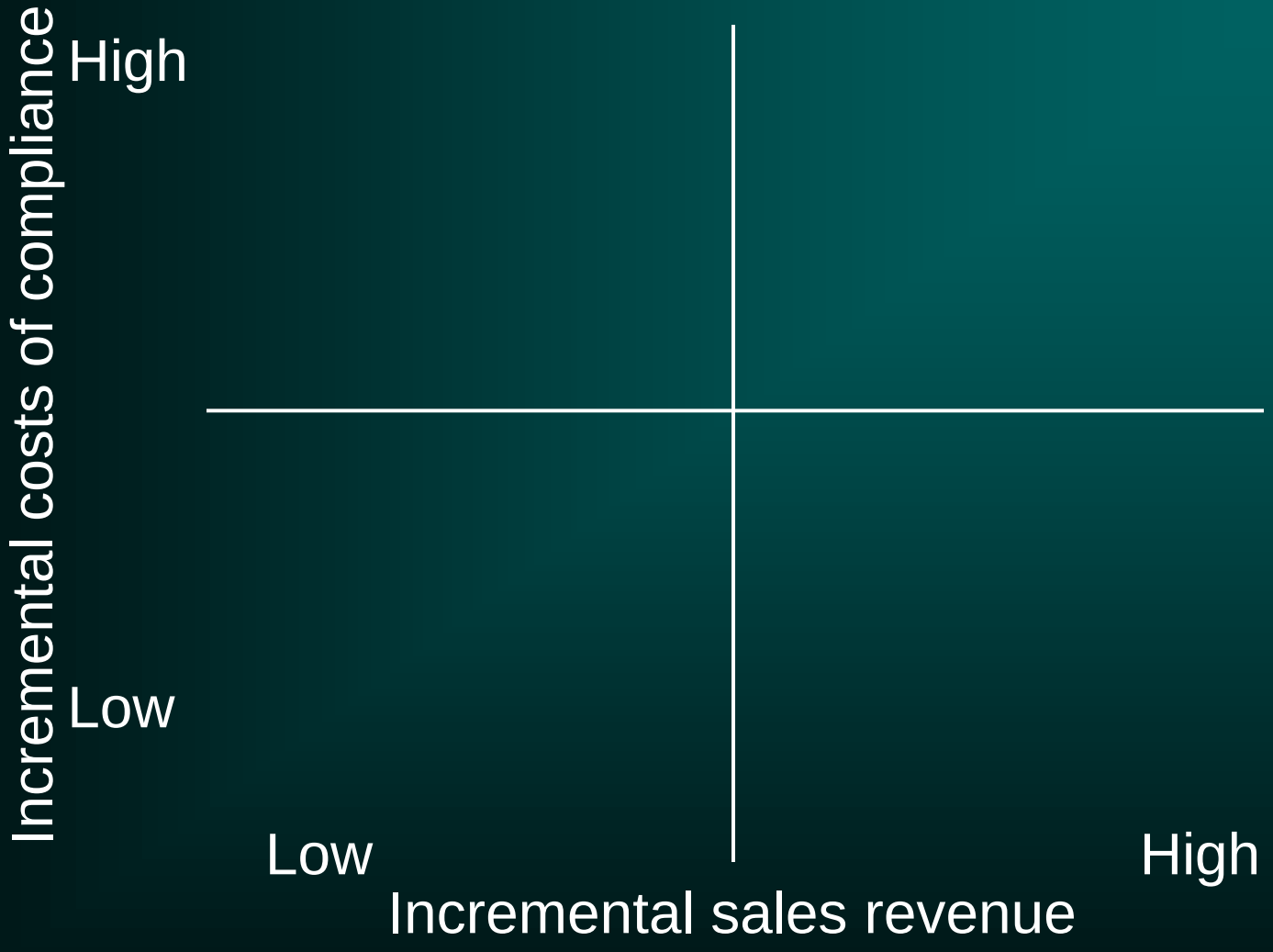
- Facilitates adoption of good review practices and exchanges between regulators
- Reduces burden of repetitive facility audits/inspections

Why seek regulatory convergence?

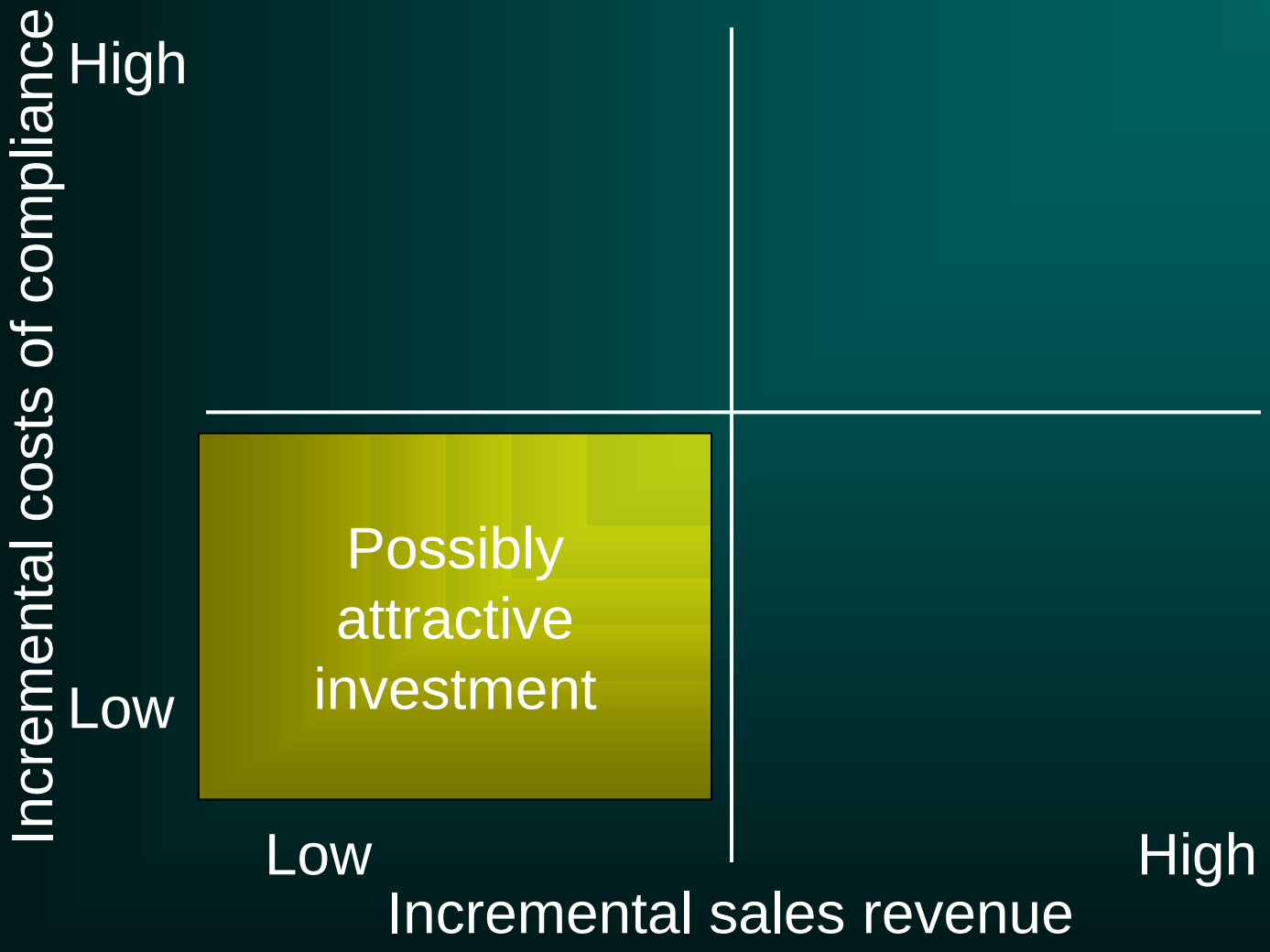
How can regulators best contribute to public health with the resources they have?

How can regulatory harmonization contribute to public confidence?

Business case



Business case



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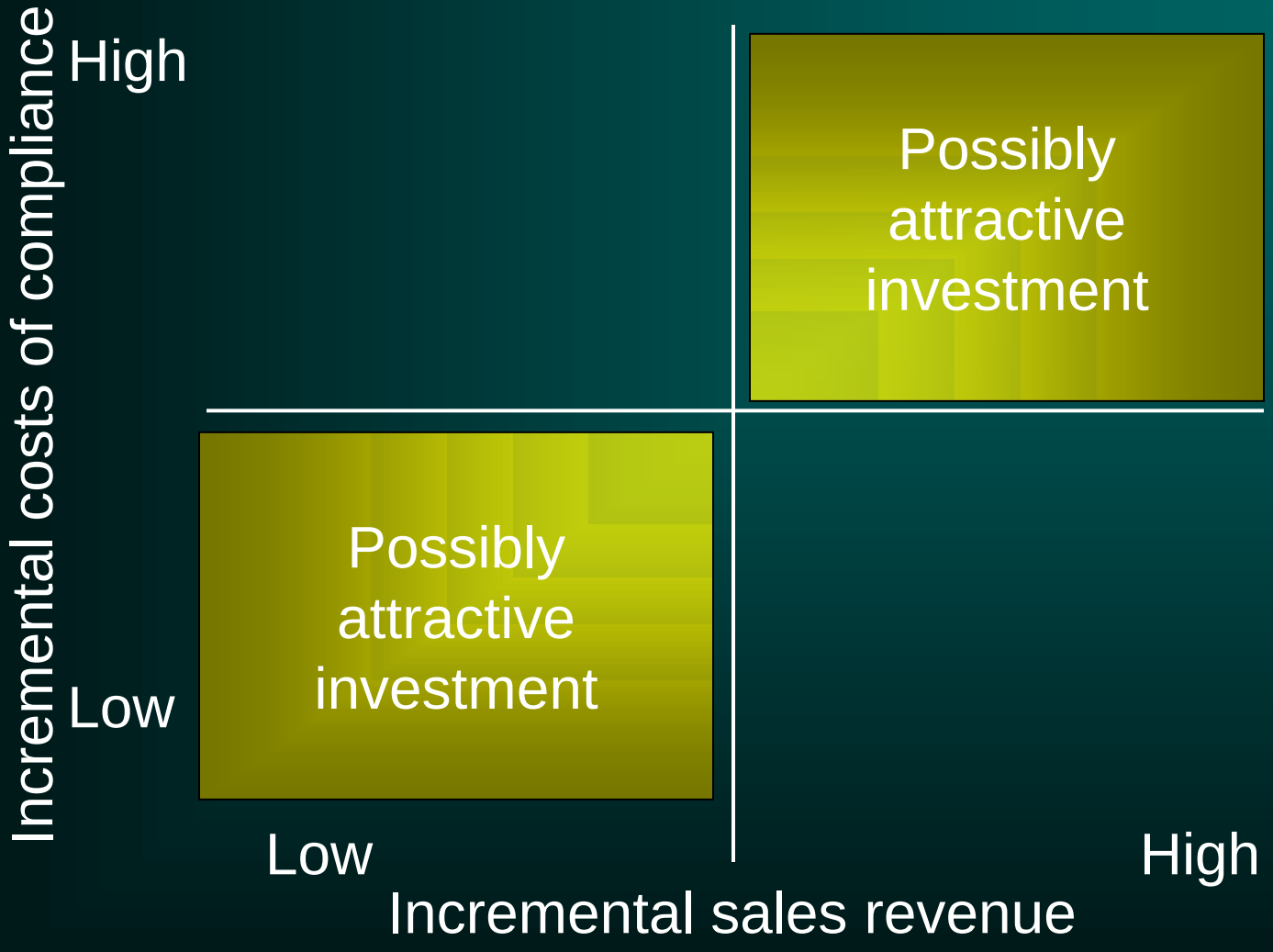

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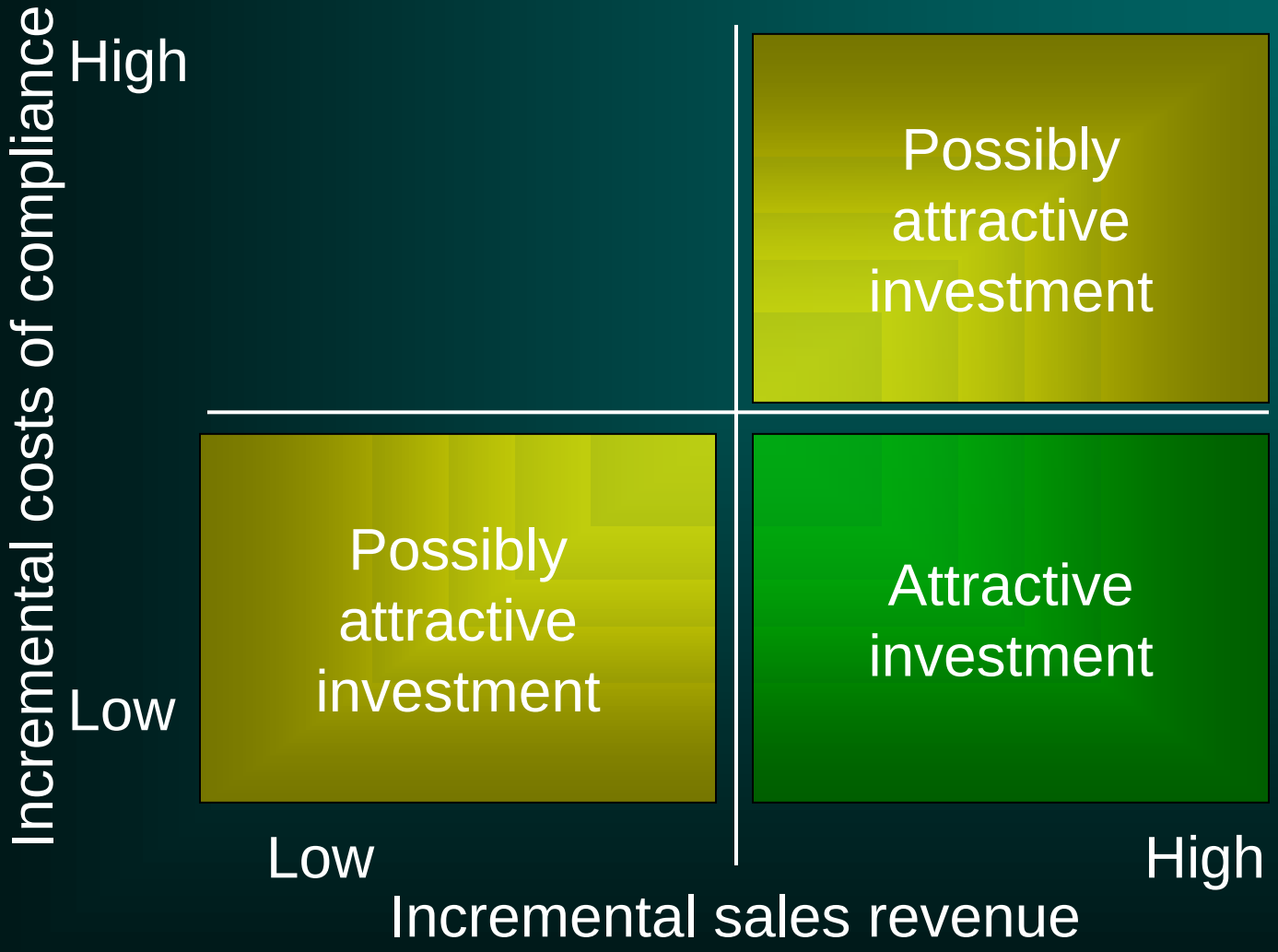

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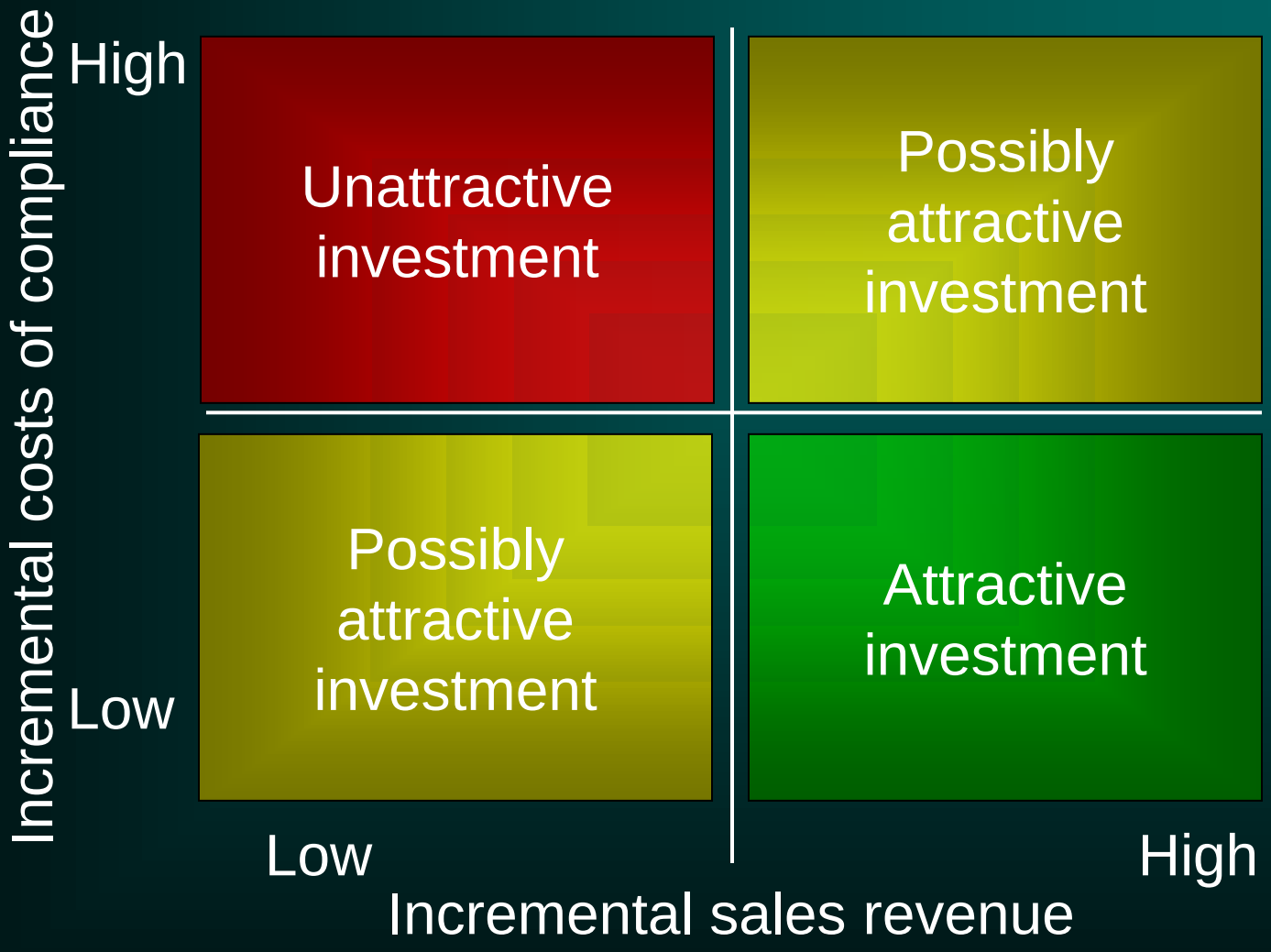

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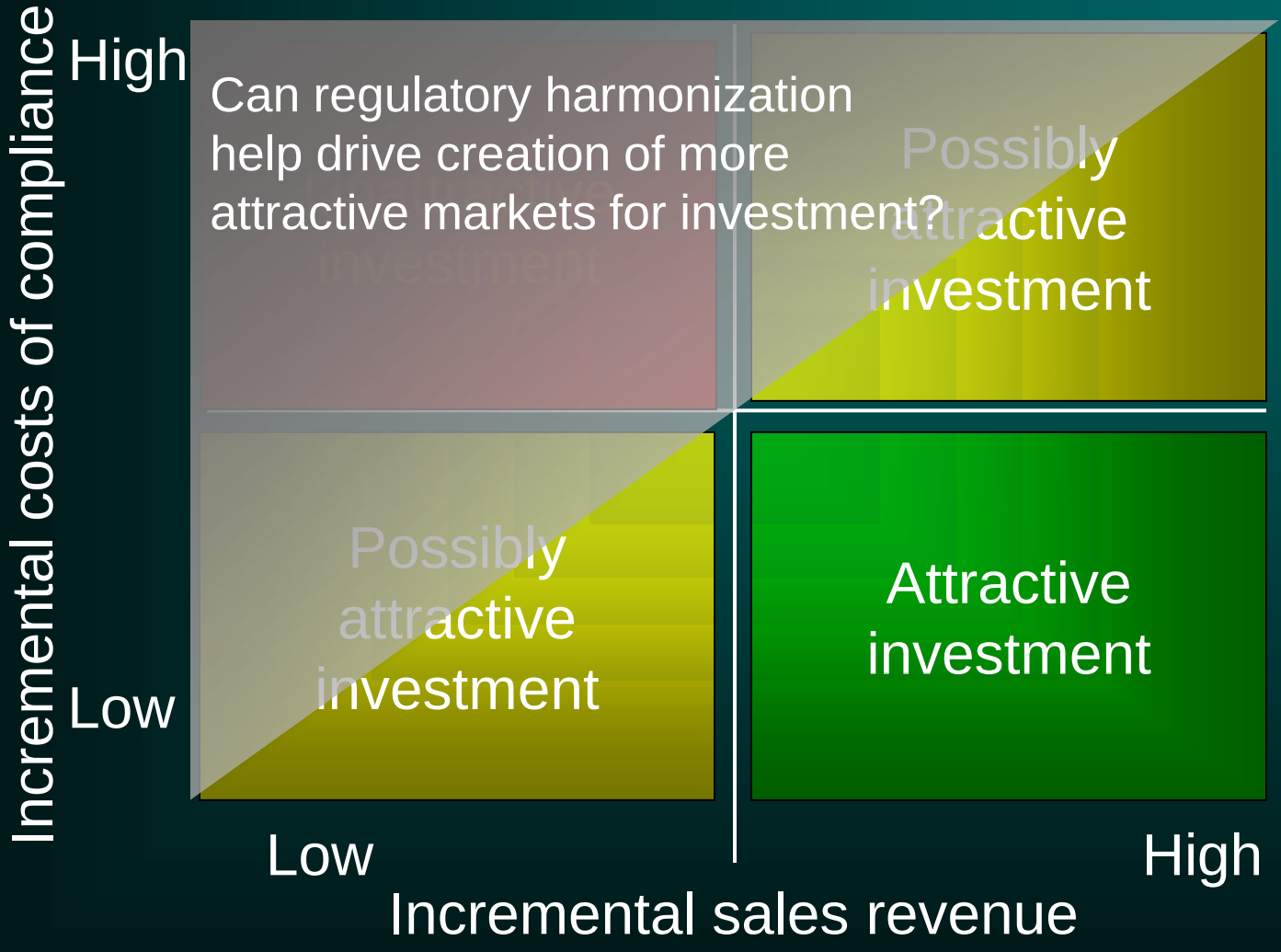

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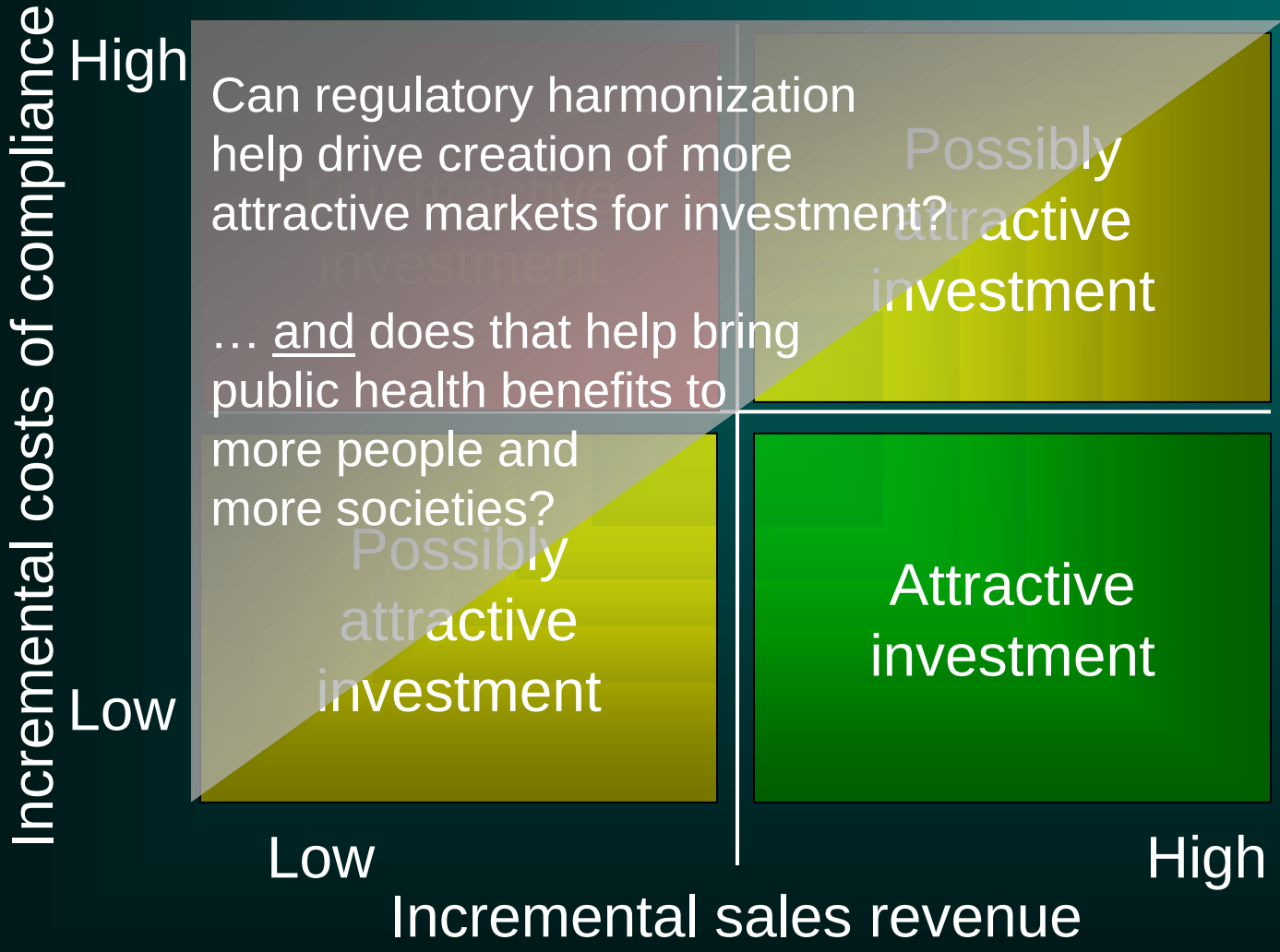

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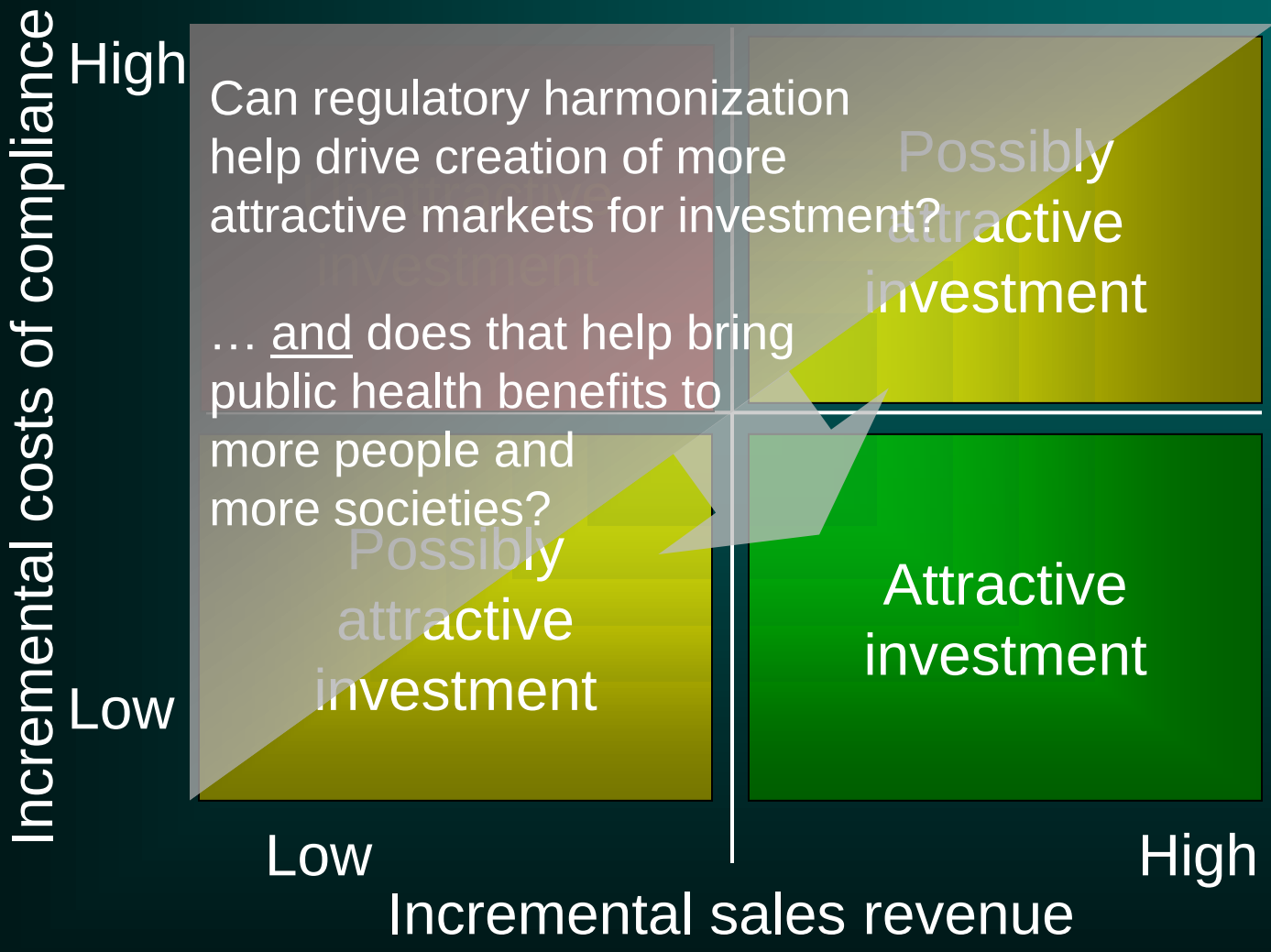


Business case

- Does regulatory harmonization benefit only “rich country” suppliers?
  - ↑ Public confidence (at home and abroad)
  - ↑ Ability to enter larger markets
  - ↑ Facilitation of trade

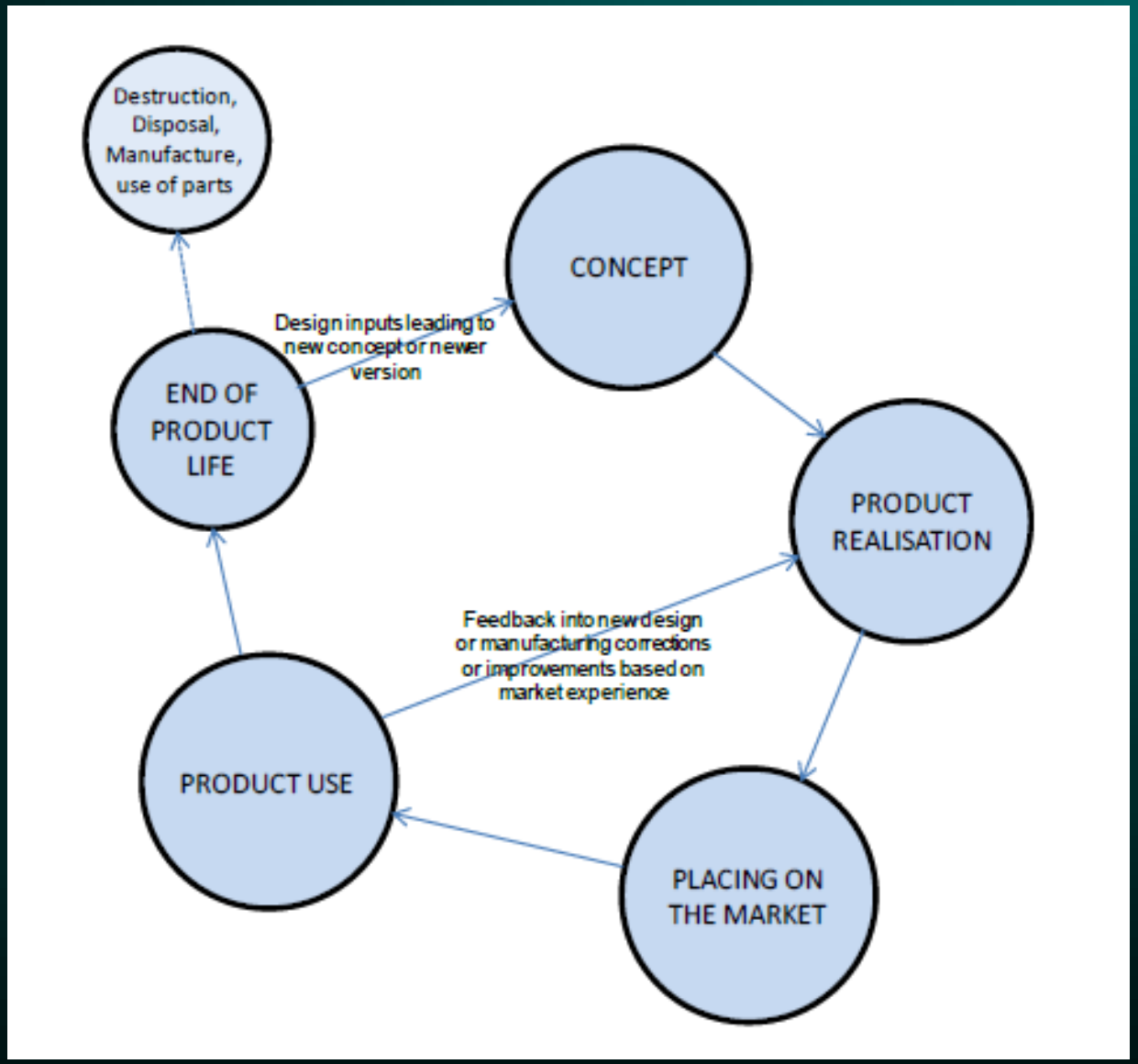
Medical device regulatory harmonization forums

Global Harmonization Task Force

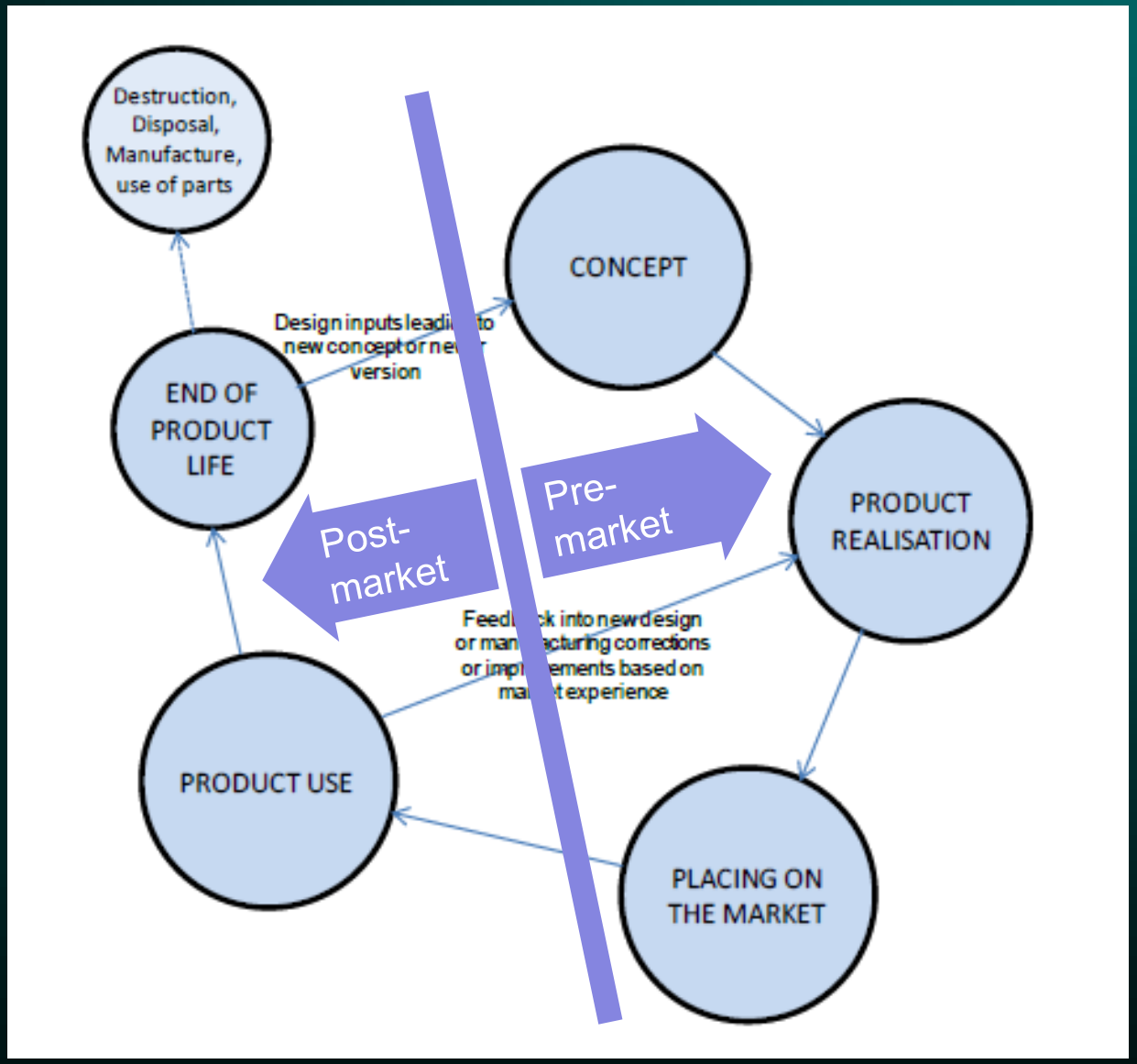
- Began in 1992 (ended in 2012)
- Voluntary forum
- Regulators and industry
- Five Founding Members:
  Australia, Canada, EU, Japan, USA
- Regional members
  AHWP
- Liaison with ISO, WHO
- Primary source of harmonized guidance documents

(now at: http://www.imdrf.org/documents/documents.asp)

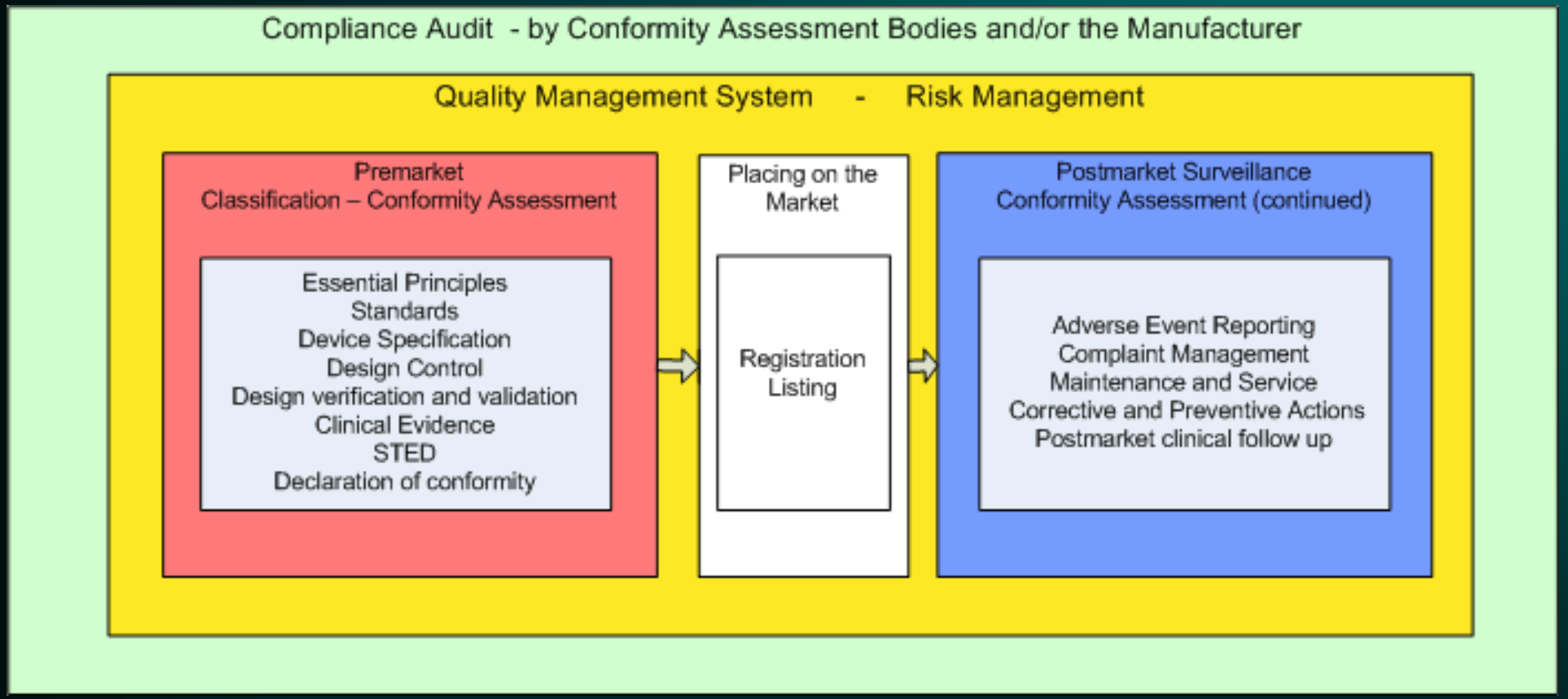
GHTF Regulatory Model



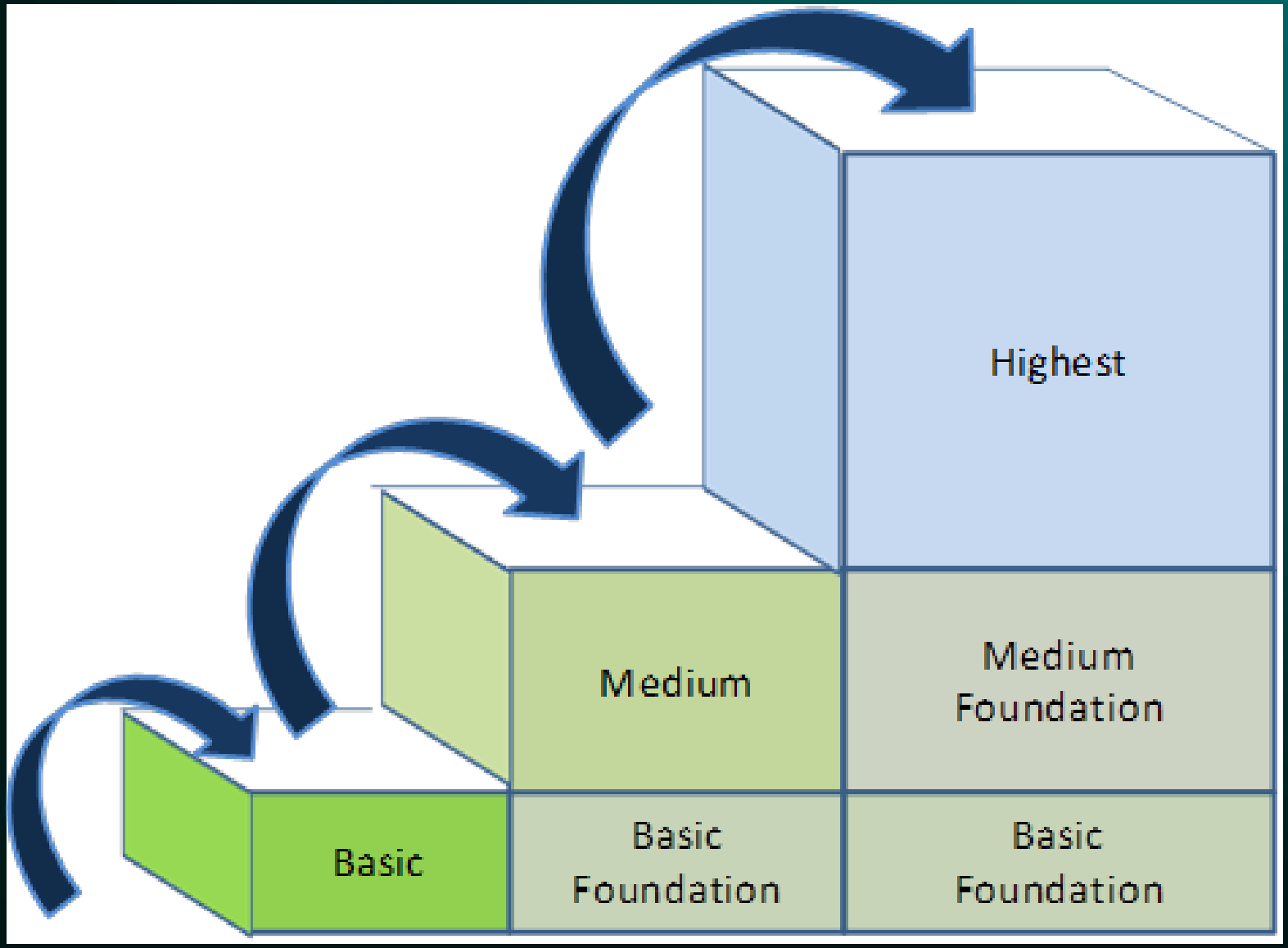
GHTF Regulatory Model



GHTF Regulatory Model



GHTF Regulatory Model



Medical device regulatory harmonization forums

Asian Harmonization Working Party

- Began in 1998
- Voluntary forum
- Regulators and industry
- 20 members
- Liaison with GHTF
- Developer of harmonized regional guidance documents based on GHTF
- www.ahwp.info

AHWP member economies

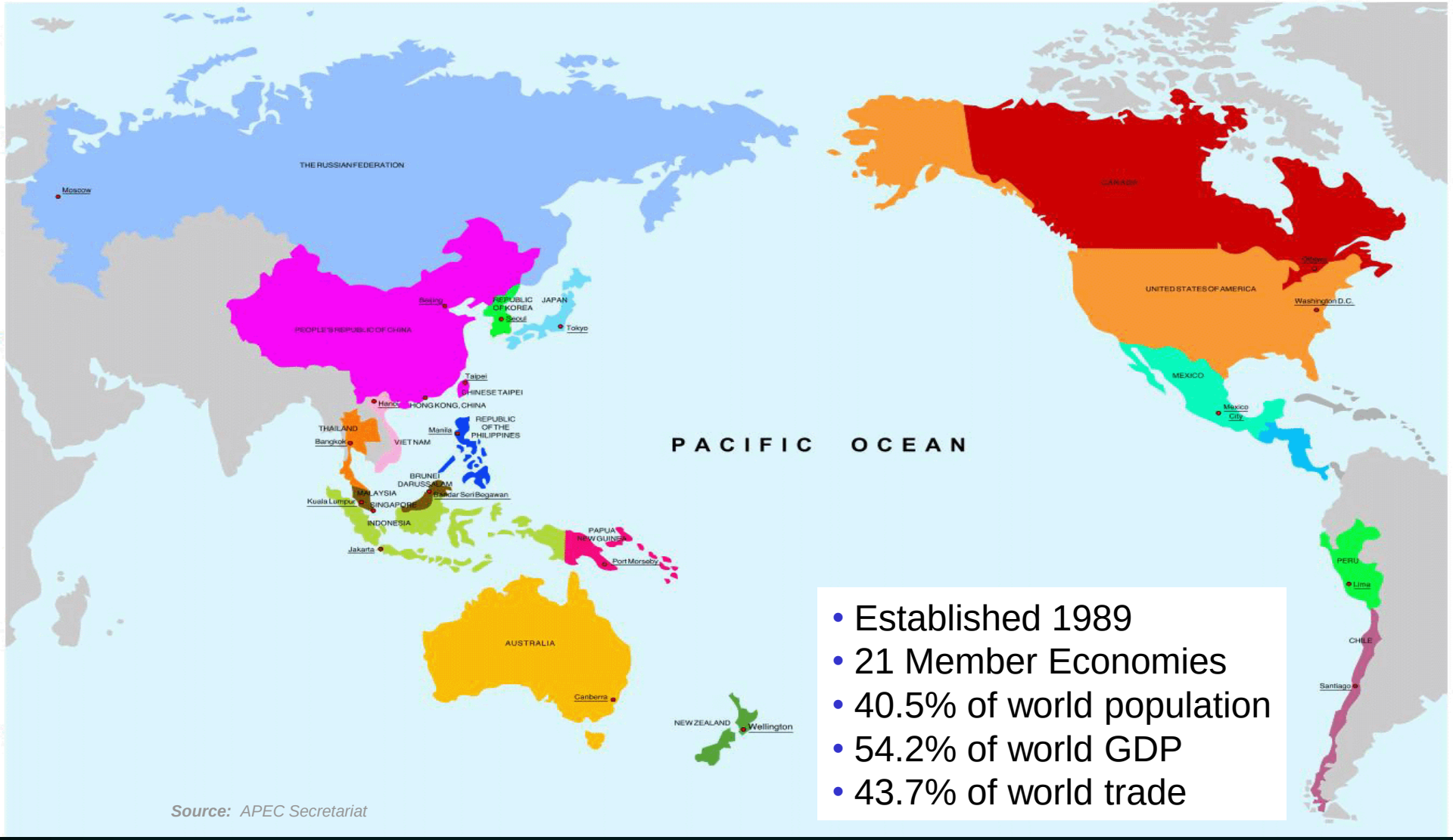
- Abu Dhabi
- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- India
- Indonesia
- Jordan
- Kingdom of Saudi Arabia
- Korea
- Lao PDR
- Malaysia
- Myanmar
- Pakistan
- People’s Republic of China
- Philippines
- Singapore
- South Africa
- Thailand
- Vietnam

Asian Harmonization Working Party

AHWP guidance

- Safety Alert Dissemination System (SADS)
- Draft Common Submission Document Template (CSDT)
- Other guidance under development

APEC MEMBER ECONOMIES



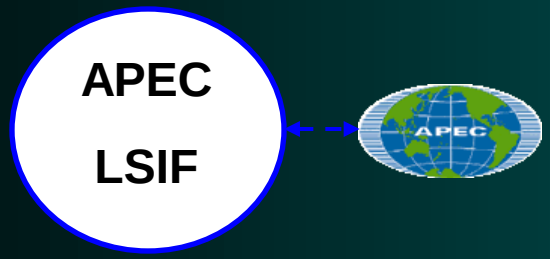
- Established 1989
- 21 Member Economies
- 40.5% of world population
- 54.2% of world GDP
- 43.7% of world trade

Source: *APEC Secretariat*

APEC Life Sciences Innovation Forum

- In 2002, APEC Leaders endorsed proposal to establish LSIF
- Reflected belief that life sciences innovation is important in promoting public health and economic development
- Annual forum to promote policy discussions and projects aimed at advancing life sciences innovation
- From outset, harmonization seen as prerequisite to promoting life sciences innovation

Medical device regulatory harmonization forums



Asia-Pacific Economic Coordination Life Sciences Innovation Forum

- Began in 2002
- Mandate from APEC Leaders
- 21 member economies
- Government, industry, academia
- http://www.apec.org/apec/apec_groups/other_apec_groups/life_sciences.html
- APEC Harmonization Center (Seoul) formed in 2009
- Regulatory Harmonization Steering Committee

APEC Harmonization Center

Association of Southeast Asian Nations (ASEAN)

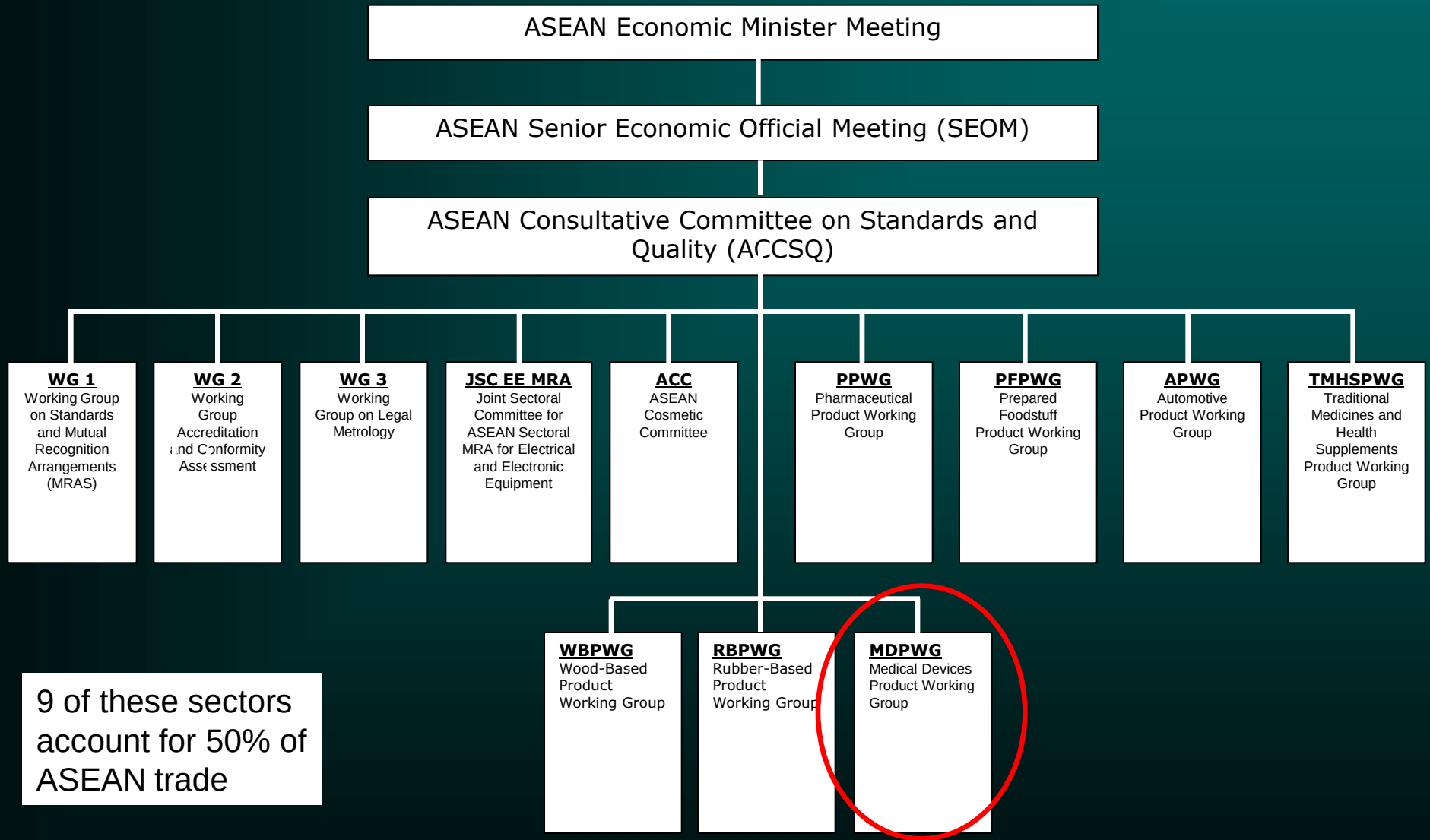
ASEAN

- Formed August 1967
  - 5 founders
  - Now 10 Member States
- ASEAN Community agreed 2003
  - ‘Single market and production base, highly competitive and fully integrated into global community by 2015’
- Three pillars
  - Political-Security Community
  - Economic Community
  - Socio-cultural Community

ASEAN economic integration

- Economic integration goals include
  - Elimination of tariffs, free movement of professionals, freer movement of capital, and streamlined customs clearance procedure
  - Elimination of non-tariff barriers to trade through harmonization of standards, technical regulations and conformity assessment procedures

ASEAN harmonising standards and regulations



9 of these sectors account for 50% of ASEAN trade

Medical device regulatory harmonization forums

Association of Southeast Asian Nations (ASEAN)
Medical Device Product Working Group

- Formed in 2004
- Mandate from ASEAN Ministers
- 10 member economies
- Government, industry
- Working to establish ASEAN Free Trade Area
- Medical device directive to take effect in 2015 (based on GHTF guidance)
- http://www.accsq-mdpwg.org/

PAHO resolution

"Resolves: …

2. To support the proposal for form an *ad hoc* group to promote and facilitate the medical devices harmonization processes in the Americas

3. To urge the Member States to:

(a) develop and strengthen their programs for the regulation of medical devices;

(b) promote and support the participation of their regulatory authorities the general meetings of the [GHTF] and those of its four study groups, while promoting the use of GHTF documents for the regulation of medical devices …"

Source: Pan American Health Organization; 42nd Directing Council; CD42/FR; 29 Sept. 2000

Medical device regulatory harmonization forums

International Medical Device Regulators Forum (IMDRF)

- Formed in 2011
- Regulators from Australia, Canada, EU, Japan, USA, Brazil, China, Russia*, and possibly India
- World Health Organization observer
- Government only (some invited industry participation in some working groups)
- http://www.imdrf.org/

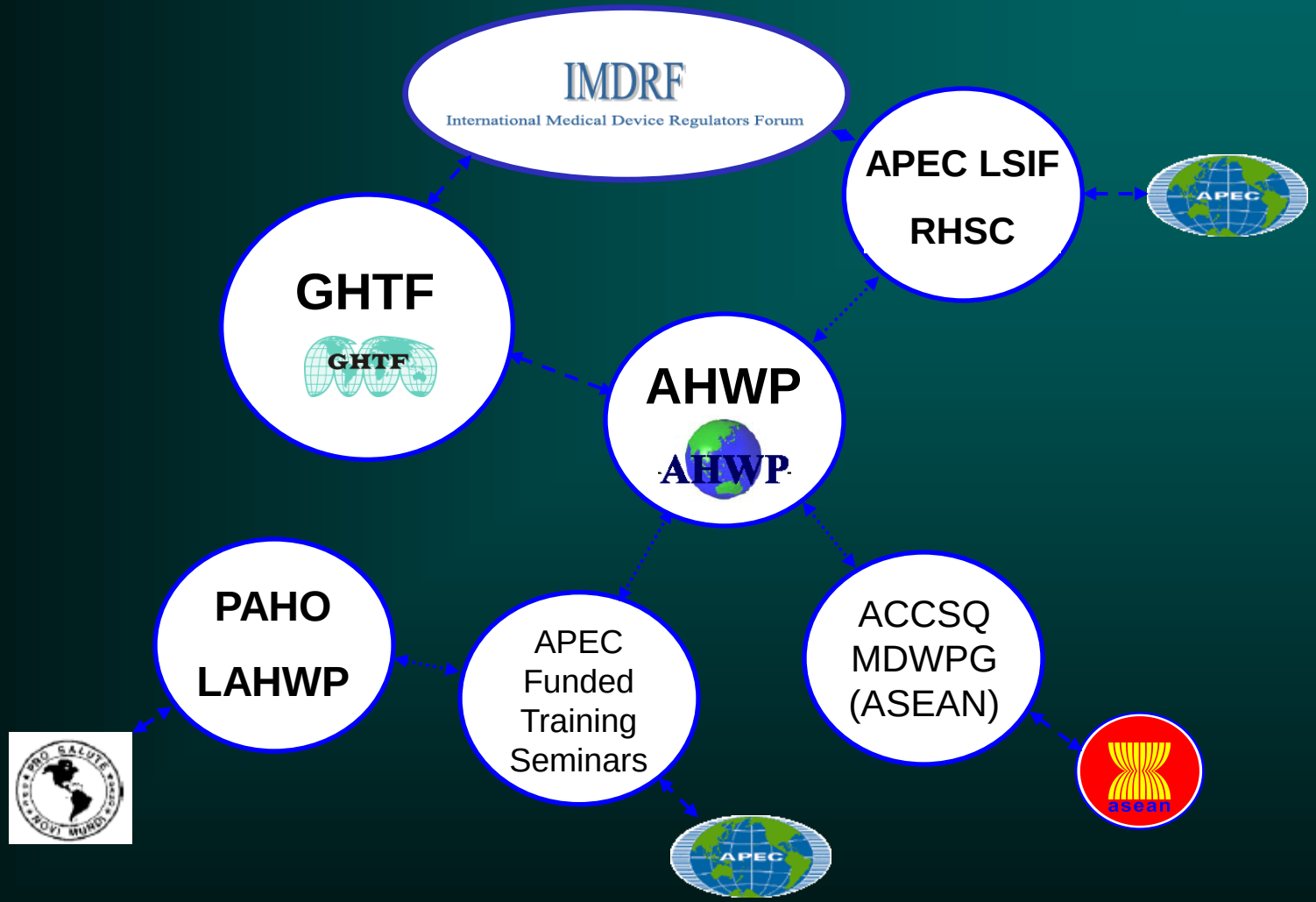
* currently observer, pending confirmation

Medical device regulatory harmonization forums

International Medical Device Regulators Forum (IMDRF)

- "… to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety"

Medical device regulatory harmonization forums



WHO guidance

Source: *Medical device regulations: Global overview and guiding principles*; World Health Organization, Geneva; 2003

WHO guidance

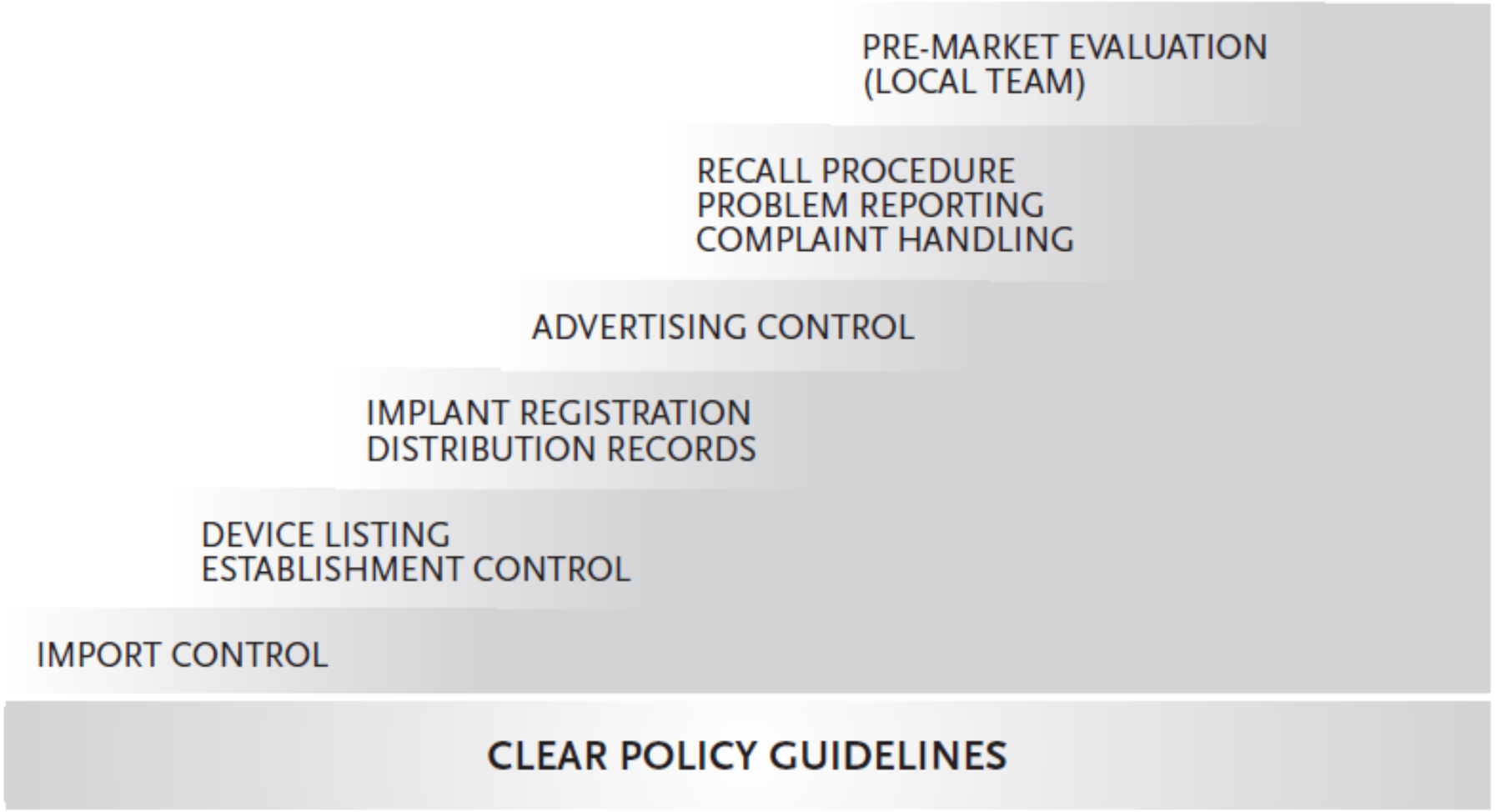
"With the exception of commercial activities including advertising and sales, …, the GHTF Study Groups are involved in all aspects that have direct impact on the safety and performance of medical devices.

Therefore, recommendations from the GHTF [study groups] can provide excellent reference or guidance for countries that are establishing medical device regulation programmes."

Source: *Medical device regulations: Global overview and guiding principles*; World Health Organization, Geneva; 2003

WHO guidance

Figure 10. Suggested priorities for regulatory programme development



Source: *Medical device regulations: Global overview and guiding principles*; World Health Organization, Geneva; 2003

Regional opportunities

- Formal and informal regulator-to-regulator cooperation (“pooling of competence”)?
- National adoption of GHTF/IMDRF guidance?
- Formal recognition of international standards (ISO and IEC)?
- Revitalize Latin America Harmonization Working Party, perhaps under PAHO?

Questions?